

2003010061

P961

**Long-term safety, efficacy, and dosing of botulinum toxin type B (Myobloc) in cervical dystonia (CD) and other movement disorders**

*R. Kumar, L.C. Seeberger (Englewood, CO, USA)*

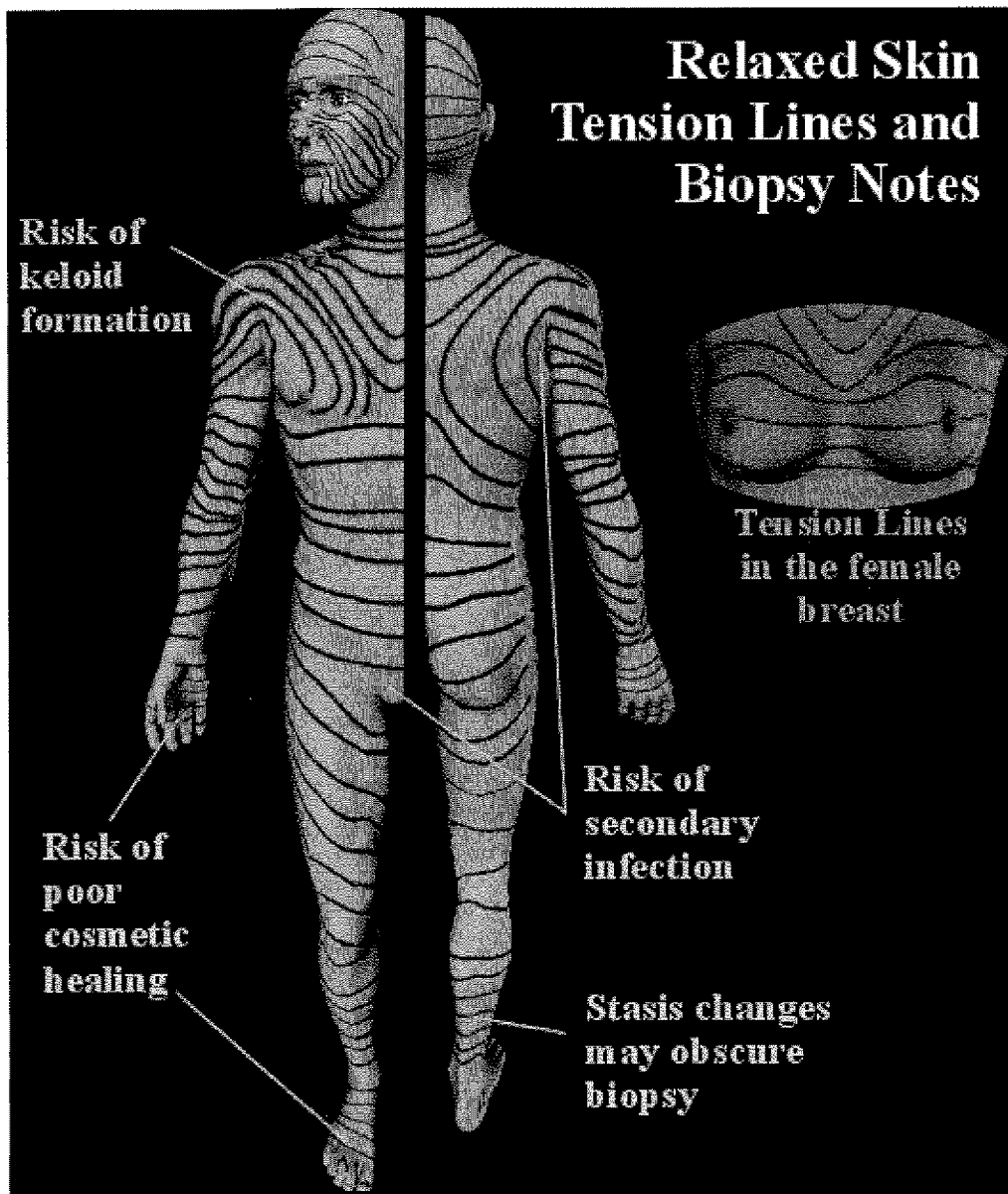
**Objective:** To describe the long-term safety, efficacy, and dosing of Myobloc.

**Background:** In short-term studies of CD, Myobloc has been demonstrated to be efficacious at doses of 10,000–15,000 U, but few long-term studies have been published and safety and efficacy of higher doses has not been established. Consensus guidelines for dosing individual muscles have been published, but confirmatory efficacy data has been lacking.

**Methods:** We reviewed our experience with 36 patients treated with Myobloc for up to 56 months. Dosing, adverse effects, development of resistance, and benefit were noted.

**Results:** Twenty-nine CD patients were treated for  $19.6 \pm 19$  months (range 3–56) with 22 considered botulinum toxin type A resistant and 9 having undergone prior denervation surgery. At last follow-up, 16 patients demonstrated ongoing benefit with repeated Myobloc dosing, 5 patients had evaluating data on only 1 set of injections, 3 patients were primary non-responders (due to severity and nature of CD), and 3 patients who previously responded to Myobloc have failed to respond to their last 1 to 2 injections (possibly resistant). Two patients with botulinum toxin type A resistance have developed definite Myobloc resistance (failure to respond to cervical muscle and frontalis injections) after 49 and 35 months of Myobloc responsiveness. Amongst responders, final total Myobloc dose was  $14,800 \pm 6,600$  U (range 2,500–25,000) and for select muscles beneficial doses were as follows: sternocleidomastoid  $2,500 \pm 1,000$  U (range 1,000–5,000); splenius capitis  $3,300 \pm 1,200$  U (range 1,250–7,500); semispinalis capitis  $1,900 \pm 900$  U (range 1,000–4,000); trapezius  $2,400 \pm 1,200$  U (range 1,000–5,000); levator scapulae  $2,400 \pm 800$  U (range 1,250–5,000); and longissimus capitis  $2,400 \pm 1,000$  U (range 1,000–3,500). Seven other patients with a variety of other movement disorders received injections of non-cervical muscles. No serious adverse events related to Myobloc were seen. Minor adverse events included dry mouth (8 patients with one injection only), dysphagia (3), injection site pain (3), and excess neck weakness (2).

**Conclusions:** Many patients with severe CD require Myobloc doses of 15,000 U or greater and can be safely and efficaciously treated with up to 25,000 U with repeated doses for up to 56 months. Diminished response to Myobloc was seen in 2 patients that had previously lost responsiveness to type A toxin.



June 22, 1983. These two papers, filed before decision, deal only with the printing of the Combined Appendix of ten volumes said to contain a total of 9,307 pages, 5,743 of which were designated by appellee after appellants had initially designated the balance. There is an excessively detailed dispute over how many of the pages designated by appellee were necessary. Appellee appears not to have contributed to the cost of printing the appendix, which cost, paid by appellants, is said to have been \$31,850.15. Federal Rule of Appellate Procedure (FRAP) 30(b) authorizes us to impose upon a party the cost of printing material "unnecessarily" included. FRAP Rule 39(a) provides that, in the absence of an order by the court, in the case of a reversal "costs shall be taxed against the appellee."

Having considered the foregoing, we have a clear appreciation of the impossibility of determining, within reason, exactly what was or was not necessarily included in the appendix in this extended and complex litigation. We conclude that, under all of the circumstances with which we have necessarily become familiar in deciding this case, it is fair and equitable that the parties share equally the cost of printing the Combined Appendix and that otherwise each party bear its own costs. In accordance with Rule 39(a), it is so ordered.

*Reversed and Remanded.*

Miller, Circuit Judge, concurring in part.

Although I agree with the majority's analysis and holding on the fraud issue, it seems appropriate to state my conclusion that, because of the unpredictability of propanil in 1957, the district court erred in granting R&H an April 4, 1957, date of conception rather than a date, concurrent with a reduction to practice, in the summer of 1957 — after the May 27, 1957, date of filing of Monsanto's application, so that the Monsanto patent constitutes a 35 U.S.C. §102(e) bar to the R&H patent. *Alpert v. Slatin*, 305 F.2d 891, 896, 134 USPQ 296, 301 (CCPA 1962).

## Court of Appeals, Federal Circuit

W.L. Gore & Associates, Inc.  
v. Garlock, Inc.

Nos. 83-613/614

Decided Nov. 14, 1983

### PATENTS

#### 1. Court of Appeals for the Federal Circuit — Weight given decision reviewed (§26.59)

Parties' argument relating to salutary injunction of FRCP 52(a) cannot be controlling on all issues, where dispositive legal error occurred in interpretation and application of patent statute, 35 USC.

#### 2. Court of Appeals for the Federal Circuit — Weight given decision reviewed (§26.59)

Findings that rest on erroneous view of law may be set aside on that basis.

#### 3. Construction of specification and claims — Claim defines invention (§22.30)

Claims measure and define invention.

#### 4. Construction of specification and claims — Combination claims (§22.35)

#### Infringement — Process patents (§39.65)

Court's restriction of claimed multi-step process to one step constitutes error, whether done at behest of patentee relying on that restriction to establish infringement by one who employs only that one step in process otherwise distinct, or at behest of accused infringer relying on that restriction to establish invalidity by showing that one step in prior art process otherwise distinct; invention must be considered as whole.

#### 5. Court of Appeals for the Federal Circuit — Weight given decision reviewed (§26.59)

CAFC is not at liberty to substitute its own for district court's findings underlying district court's conclusion that claim is invalid.

#### 6. Patentability — Anticipation — Process (§51.225)

It is irrelevant that those using invention may not have appreciated results where patent owner's operation of device is consistent, reproducible use of claimed invention; were that alone enough to prevent anticipation, it would be possible to obtain patent for old and unchanged process.

**7. Use and sale — Extent and character of use (§69.5)**

Nonsecret use of claimed process in usual course of producing articles for commercial purposes is public use.

**8. Use and sale — Extent and character of use (§69.5)**

Patentees' commercialization of product produced by its patented process can result in forfeiture of patent granted them for that process on application filed by them more than one year later; however, their secret commercialization of process cannot be bar to patent grant on that process.

**9. Patent grant — Intent of patent laws (§50.15)**

Early public disclosure is linchpin of patent system.

**10. Interference — Priority (§41.70)**

Law disfavors prior inventor who benefits from process by selling its product but suppresses, conceals, or otherwise keeps process from public, as against later inventor who promptly files patent application from which public will gain disclosure of process.

**11. Patentability — Evidence of — In general (§51.451)**

District court that in its consideration of prior art disregarded unpredictability and unique nature of product to which claimed inventions relate errs.

**12. Construction of specification and claims — By prior art (§22.20)**

District court that in its consideration of prior art considers claims in less than their entireties errs.

**13. Patentability — Evidence of — Suggestions of prior art (§51.469)**

District court that considers references in less than their entireties, i.e., in disregarding disclosures in references that diverge from and teach away from invention at hand, errs.

**14. Construction of specification and claims — Comparison with other claims (§22.40)**

Claims must be considered individually and separately.

**15. Patentability — Anticipation — Combining references (§51.205)**

There must have been something present in teachings in references to suggest to one skilled in art that claimed invention before court would have been obvious.

**16. Patentability — Evidence of — Suggestions of prior art (§51.469)**

Fact that patentee proceeded contrary to accepted wisdom of prior art is strong evidence of nonobviousness.

**17. Patentability — Tests of — Skill of art (§51.707)**

Imbuing one of ordinary skill in art with knowledge of invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to insidious effect of hindsight syndrome wherein that which only inventor taught is used against its teacher.

**18. Patentability — Invention — In general (§51.501)**

**Patentability — Tests of — Skill of art (§51.707)**

Decisionmaker must forget what he or she has been taught at trial about claimed invention and cast mind back to time invention was made to occupy mind of one skilled in art who is presented only with references, and who is normally guided by then-accepted wisdom in art.

**19. Pleading and practice in courts — Burden of proof — Validity (§53.138)**

**Presumption for patent grant — Patent Office consideration of prior art (§55.5)**

It is not law that presumption of validity is weakened greatly where Patent Office has failed to consider pertinent prior art; presumption has no separate evidentiary value; it cautions decisionmaker against rush to conclude invalidity; submission of additional art that is merely "pertinent" does not dispel that caution; however, inescapable burden of persuasion on one who would prove invalidity remains throughout trial.

**20. Pleading and practice in courts — Burden of proof — Validity (§53.138)**

**Presumption from patent grant — Patent Office consideration of prior art (§55.5)**

Burden of proving invalidity may be facilitated by prior art that is more pertinent than that considered by PTO.

**21. Patentability — Evidence of — In general (§51.451)**

District court that specifically declines to consider objective evidence of nonobviousness errs; that evidence can often serve as insu-

ance against insidious attraction of siren hindsight when confronted with difficult task of evaluating prior art; even when prior art evidence points more in direction of nonobviousness than obviousness, objective evidence may tend to reassure decisionmaker.

**22. Patentability — Anticipation — In general (§51.201)**

Anticipation requires disclosure in single prior art reference of each element of claim under consideration.

**23. Patentability — Anticipation — Process (§51.225)**

**Patentability — Composition of matter (§51.30)**

Anticipation of inventions set forth in product claims cannot be predicated on mere conjecture respecting characteristics of products that might result from practice of processes disclosed in references.

**24. Patentability — Anticipation — Infringement as test (§51.211)**

Accused infringer's employment of process of dominating patent is not anticipation of invention described and claimed in improvement patent.

**25. Patentability — Anticipation — In general (§51.201)**

**Patentability — Invention — In general (§51.501)**

Inherency and obviousness are distinct concepts.

**26. Patentability — Evidence of — In general (§51.451)**

All evidence bearing on obviousness issue, as with any other issue raised in conduct of judicial process, must be considered and evaluated before required legal conclusion is reached.

**27. Patentability — Evidence of — In general (§51.451)**

Objective evidence of nonobviousness, i.e., "indicia" of *Graham v. John Deere Co.*, 148 USPQ 459, may in given case be entitled to more weight or less, depending on its nature and its relationship to invention's merits; it may be most pertinent, probative, and revealing evidence available to aid in reaching conclusion on obvious/nonobvious issue.

**28. Patentability — Evidence of — Commercial success — In general (§51.4551)**

Praise greeting products claimed in patent from suppliers, including owner of prior art

patent, is objective evidence of nonobviousness.

**29. Patentability — Composition of matter (§51.30)**

Claim to new product is not required to include critical limitations.

**30. Specification — Sufficiency of disclosure (§62.7)**

Patents are written to enable those skilled in art to practice invention, not public, and Section 112 speaks as of application filing date, not as of time of trial.

**31. Specification — Sufficiency of disclosure (§62.7)**

Section 112 requires that inventor set forth best mode of practicing invention known to him at time application was filed.

**32. Claims — Indefinite — In general (§20.551)**

Use of "stretching at rate exceeding specific percent per second" in claims is not indefinite.

**33. Claims — Specification must support (§20.85)**

It is claimed invention for which enablement is required.

**34. Specification — Sufficiency of disclosure (§62.7)**

Patent is not invalid merely because some experimentation is needed; patent is invalid only when those skilled in art are required to engage in undue experimentation to practice invention.

**35. Construction of specification and claims — Claim defines invention (§22.30)**

Distinguishing what infringes from what does not is role of claims, not of specification.

**36. Construction of specification and claims — Defining terms (§22.45)**

Patent applicant can be his own lexicographer.

**37. Defenses — Fraud (§30.05)**

Fraud must be shown by clear and convincing evidence; state of mind of one making representations is most important of elements to be considered in determining existence of fraud; good faith and subjective intent, while they are to be considered, should not necessarily be made controlling; under ordinary circumstances, fact of misrepresentation coup-

led with proof that party making it had knowledge of its falsity is enough to warrant drawing inference that there was fraudulent intent; where public policy demands complete and accurate disclosure it may suffice to show nothing more than that misrepresentations were made in atmosphere of gross negligence as to their truth.

**38. Pleading and practice in courts — Issues determined — Validity and infringement (§53.505)**

Better practice is for district court to decide both validity and infringement issues when both are contested at trial, enabling conduct of single appeal and disposition of entire case in single appellate opinion.

**39. Infringement — Tests of — Comparison with claim (§39.803)**

Infringement is decided with respect to each asserted claim as separate entity.

**Particular patents — Porous Products**

3,953,566, Gore, Process for Producing Porous Products, holding of invalidity of claims 3 and 19 reversed and of claims 1 and 17 affirmed.

4,187,390, Gore, Porous Products and Process Therefor, holding of invalidity reversed.

Appeal from District Court for the Northern District of Ohio, Manos, J.; 220 USPQ 220.

Consolidated actions by W. L. Gore & Associates, Inc., against Garlock, Inc., for patent infringement, in which defendant counterclaims for declaratory judgment of patent invalidity, noninfringement, fraudulent solicitation, and entitlement to attorney fees. From judgment for defendant, plaintiff appeals and defendant cross-appeals. Affirmed in part, reversed in part, and remanded; Davis, Circuit Judge, concurring in result in part and dissenting in part, with opinion.

David H. Pfeffer, New York, N.Y. (J. Robert Dailey and Janet Dore, both of New York, N.Y., and John S. Campbell, Newark, Del., of counsel) for appellant.

John J. Mackiewicz, Philadelphia, Pa. (Dale M. Heist, Philadelphia, Pa., on the brief, Bernard Ouziel, New York, N.Y., of counsel) for appellee.

Before Markey, Chief Judge, and Davis and Miller, Circuit Judges.

Markey, Chief Judge.

Appeal from a judgment of the District Court for the Northern District of Ohio holding U.S. Patents 3,953,566 ('566) and 4,187,390 ('390) invalid. We affirm in part, reverse in part, and remand for a determination of the infringement issue.

*Background*

Tape of unsintered polytetrafluorethylene (PTFE) (known by the trademark TEFLON of E.I. du Pont de Nemours, Inc.) had been stretched in small increments. W. L. Gore & Associates, Inc. (Gore), assignee of the patents in suit, experienced a tape breakage problem in the operation of its "401" tape stretching machine. Dr. Robert Gore, Vice President of Gore, developed the invention disclosed and claimed in the '566 and '390 patents in the course of his effort to solve that problem. The 401 machine was disclosed and claimed in Gore's U.S. Patent 3,664,915 ('915) and was the invention of Wilbert L. Gore, Dr. Gore's father. PTFE tape had been sold as thread seal tape, i.e., tape used to keep pipe joints from leaking. The '915 patent, the application for which was filed on October 3, 1969, makes no reference to stretch rate, at 10% per second or otherwise, or to matrix tensile strength in excess of 7,300 psi.

Dr. Gore experimented with heating and stretching of highly crystalline PTFE rods. Despite slow, careful stretching, the rods broke when stretched a relatively small amount. Conventional wisdom in the art taught that breakage could be avoided only by slowing the stretch rate or by decreasing the crystallinity. In late October 1969, Dr. Gore discovered, contrary to that teaching, that stretching the rods as fast as possible enabled him to stretch them to more than ten times their original length with no breakage. Further, though the rod was thus greatly lengthened, its diameter remained virtually unchanged throughout its length. The rapid stretching also transformed the hard, shiny rods into rods of a soft, flexible material.

Gore developed several PTFE products by rapidly stretching highly crystalline PTFE, including: (1) porous film for filters and laminates; (2) fabric laminates of PTFE film bonded to fabric to produce a remarkable material having the contradictory properties of impermeability to liquid water and permeability to water vapor, the material being used to make "breathable" rainwear and filters; (3) porous yarn for weaving and braiding into other products, like space suits and pump packing; (4) tubes used as replacements for human arteries and veins; and (5) insulation for high performance electric cables.

On May 21, 1970, Gore filed the patent application that resulted in the patents in suit. The '566 patent has 24 claims directed to processes for stretching highly crystalline, unoriented, PTFE. The processes, *inter alia*, include the steps of stretching PTFE at a rate above 10% per second and at a temperature between about 35°C and the crystalline melt point of PTFE. The '390 patent has 77 claims directed to various products obtained by processes of the '566 patent.

It is effectively undisputed that the present inventions filled a long sought yet unfilled need. The United States Army and the research director of a Garlock Inc. (Garlock) customer had been looking for and following up every remote lead to a waterproof/breathable material for many years.

It is undisputed that the present inventions enjoyed prompt and remarkable commercial success due to their merits and not to advertising or other extraneous causes.

It is undisputed that the inventions provide the most important synthetic material available for use in vascular surgery, hundreds of thousands of persons having received artificial arteries formed of the patented products since 1976, and that the patented products have unique properties useful in other medical procedures, in communications satellites, radar systems, and electrical applications.

It is undisputed that the major sources of PTFE, ICI and du Pont, greeted the patented products as "magical," "bewitching," "a remarkable new material," and one that "differs from other processed forms of Teflon."

It is undisputed that the patented products were met with skepticism and disbelief by at least one scientist who had worked with PTFE at du Pont for many years and who testified as an expert at trial.

It is undisputed that Garlock first produced an accused product in response to a customer's request for a substitute for the patented product, that Garlock advertised its accused product as a "new form" of PTFE and as "a versatile new material which provides new orders of performance for consumer, industrial, medical and electrical applications," and that the customer describes that accused product as "a new dimension in rainproof/breathable fabrics."

#### Proceedings

On Nov. 2, 1979, Gore sued Garlock for infringement of process claims 3 and 19 of the '566 patent, and sought injunctive relief, damages and attorney fees. Garlock counterclaimed on Dec. 18, 1979, for a declaratory judgment of patent invalidity, non-infringe-

ment, fraudulent solicitation, and entitlement to attorney fees. On Feb. 7, 1980, Gore filed a second suit for infringement of product claims 14, 18, 36, 43, 67 and 77 of the '390 patent. In light of a stipulation, the district court consolidated the two suits for trial.

Gore alleged infringement of certain claims by certain products:

'566 patent claims	'390 patent claims	Garlock Product
19	14, 43	film
--	36, 77	laminates
19	18	yarn
--	67	braided packing
3	--	tape

At trial, Garlock addressed only claims 1, 3, 17, and 19 of the '566 patent and claims 1, 9, 12, 14, 18, 35, 36, 43, 67 and 77 of the '390 patent. See Appendix to this opinion.

The district court, in a thorough memorandum accompanying its judgment, and in respect of the '566 patent: (1) found claim 1 anticipated under 35 U.S.C. §102(a) by Gore's use of its 401 machine and use by the Budd Company (Budd) of a Cropper machine; (2) declared all claims of the patent invalid under 102(b) because the invention had been in public use and on sale more than one year before Gore's patent application, as evidenced by Budd's use of the Cropper machine; (3) held claims 1, 3, 17 and 19 invalid for obviousness under 35 U.S.C. §103, on the basis of various reference pairings: (a) Japanese patent 13560/67 (Sumitomo) with U.S. patent 3,214,503 (Markwood); (b) U.S. patent 2,776,465 (Smith) with Markwood; or (c) Gore's '915 patent with Sumitomo; and (4) held all claims invalid as indefinite under 35 U.S.C. §112.

35 U.S.C. §102(a) and (b) provide:

A person shall be entitled to a patent unless —

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or \*\*\*

35 U.S.C. §103 provides:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

In its opinion respecting the '390 patent, the district court held: (1) claims 1, 9, 12, 14, 18, 35, 36, 43, 67 and 77 invalid §§102 and 103 in view of Sumitomo and Smith; and (2) all claims invalid as indefinite under §112.

The court found that Gore did not commit fraud before the Patent and Trademark Office (PTO), denied Garlock's request for attorney fees, and refrained from deciding the infringement issue.

#### Issues

Did the district court err in: (1) its holding of invalidity under §§102(a), 102(b), 103 and 112; (2) its finding that Gore did not commit fraud on the PTO; or (3) denying attorney fees.

#### Opinion

This hard fought and bitterly contested case involved over two years of discovery, five weeks of trial, the testimony of 35 witnesses (19 live, 16 by deposition), and over 300 exhibits. The district court issued an exhaustive 37-page memorandum opinion reflective of a careful, conscientious approach to the determination of the many issues presented at trial.

The record on appeal consists of 2000 pages. The parties' briefs total 199 pages. In those briefs, counsel repeatedly accuse each other of numerous and serious breaches of the duty of candor owed the court. Each cites instances in which the testimony, the findings, and the record are or are said to be quoted in part and out of context. As a result, the usefulness and reliability of the briefs as means of informing the court has been greatly diminished if not destroyed, and careful, time-consuming study of all exhibits and each page of the record has been required.

35 U.S.C. §112 provides:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention. A claim may be written in independent or dependent form, and if in dependent form, it shall be construed to include all the limitations of the claim incorporated by reference into the dependent claim.

Appellant cited 80 prior court opinions in its main brief. Appellee's brief totally ignores all but two of those citations, but adds 57 more. Appellant's reply brief cites 126 prior court opinions, 34 earlier cited, 67 newly cited, and 25 of those cited by appellee. Appellee's reply brief cites 17 prior court opinions, 4 earlier cited, 7 newly cited, and 6 of the 147 cited by appellant. Accordingly, 211 prior court opinions have been evaluated in relation to the proof found in the record.

In light of the entire record and the applicable law, we are convinced that Garlock failed to carry its burden of proving all claims of the present patents invalid.

#### Standard of Review

[1,2] Where, as here, dispositive legal error occurred in interpretation and application of the patent statute, 35 U.S.C., the parties' arguments relating to the salutary injunction of Fed. Rule Civ. P. 52(a) cannot be controlling on all issues. Though findings that "rest on an erroneous view of the law may be set aside on that basis," *Pullman-Standard v. Swint*, 456 U.S. 273 (1982), it is unnecessary here to set aside any probative fact found by the district court or to engage in what would be an inappropriate reweighing of the facts.

Among the legal errors extant in the record, each of which is discussed below, are (1) the invention set forth in each claim was not in each instance considered as a whole; (2) 35 U.S.C. §102(b) was applied though criteria for its application were not present; (3) the references were not assessed in their entireties; (4) an inherency theory under §§102 and 103 was inappropriately applied; (5) that which only the inventor taught was attributed to the prior art; (6) individual steps in prior art processes dealing with materials distinct from those with which the present inventions dealt were erroneously equated to steps in the claimed processes; (7) objective evidence of nonobviousness was disregarded; and (8) the function and application of §112 were misconstrued.

Because it permeated so much of the district court's analysis, we note more fully its frequent restriction of its consideration to 10% per second rate of stretching, which it called the "thrust of the invention." That approach is repeated throughout Garlock's briefs, which refer repeatedly to the "thrust of the invention," to "the inventive concept," and to the claims "shorn of their extraneous limitations." That facile focusing on the "thrust," "concept," and "shorn" claims, resulted in treating the claims at many points as though they read differently from those actually allowed and in suit.

[3] It is true that Dr. Gore emphasized rapid stretching, for example, as well as the amount of stretch and other process limitations, during prosecution of the application for the '566 patent. Yet it is the claims that measure and define the invention. *Aro Manufacturing Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 339, 128 USPQ 354 (1961); *Bowser, Inc. v. U.S.*, 388 F.2d 346, 349, 156 USPQ 406, 409 (Cl. Cl. 1967).

[4] Each claimed invention must be considered as a whole. 35 U.S.C. §103; *Schenck, A.G. v. Nortron Corp.*, 218 USPQ 698, 700 (Fed. Cir. 1983). In determining obviousness, there is "no legally recognizable or protected 'essential,' 'gist,' or 'heart' of the invention." *Aro*, 365 U.S. at 345. A court's restriction of a claimed multi-step process to one step constitutes error, whether done at the behest of a patentee relying on that restriction to establish infringement by one who employs only that one step in a process otherwise distinct, or at the behest of an accused infringer relying on that restriction to establish invalidity by showing that one step in a prior art process otherwise distinct.

(1) Invalidity

(a) '566 Patent

(i) §102(a) and The 401 Machine

It is undisputed that the district court held only claim 1 of the '566 patent to have been anticipated under §102(a) by operation of the 401 machine in the Gore shop before Dr. Gore's invention in late October 1969. It did so on the deposition testimony of two former Gore employees, documents, and drawings of the 401 machine.

In August 1969, Gore offered to sell to Export Tool Company (Export) tape "to be made" on the 401 machine. Tape made on the 401 machine was shipped to Export on October 24, 1969. The trial judge found the rolls on the 401 machine were, at least at some point in time before October 1969, spaced less than four feet apart and that the rate of stretch accomplished in operating that machine (admittedly operated in accord with the description of machine operation in the '915 patent) must have been greater than 10% per second. The district court credited testimony that Teflon 6-c, a highly crystalline form of Teflon, was used because it was the standard resin at the time, and that the tape was stretched at a temperature above 35°C. Thus it cannot be said that the record fails to support the district court's finding that the

limitations of claim 1 were met by Gore's operation of the 401 machine before Dr. Gore's asserted "late October 1969" date of invention. Though he was working with the operation of the 401 machine, Dr. Gore offered no proof that his invention date was before the date of shipment to Export.

[5] Gore, seeking a review here of the evidence, points to certain inadequacies as indicating a failure to meet the required clear and convincing standard under §102(a). At the time of trial, the district court, bound by precedent then applicable, applied a preponderance of the evidence test. Gore asserts, erroneously, that the clearly erroneous standard does not therefore apply on this appeal. Gore does not, however, point to any basis on which the district court's findings must be held to have been clearly erroneous under the clear and convincing standard. We are not at liberty, of course, to substitute our own for the district court's findings underlying its conclusion that claim 1 is invalid.

[6] Gore's operation of the 401 machine must thus be viewed as a consistent, reproducible use of Dr. Gore's invention as set forth in claim 1, and it is therefore irrelevant that those using the invention may not have appreciated the results. *General Electric Co. v. Jewel Incandescent Lamp Co.*, 326 U.S. 242, 248, 67 USPQ 155, 157-58 (1945). Were that alone enough to prevent anticipation, it would be possible to obtain a patent for an old and unchanged process. *Ansonia Brass & Copper Co. v. Electric Supply Co.*, 144 U.S. 11, 18 (1892); see, *H.K. Regar & Sons, Inc. v. Scott & Williams, Inc.*, 63 F.2d 229, 231, 17 USPQ 81, 83 (2d Cir. 1933).

[7] The nonsecret use of a claimed process in the usual course of producing articles for commercial purposes is a public use. *Electric Storage Battery Co. v. Shimadzu*, 307 U.S. 5, 20, 41 USPQ 155, 161 (1939), and there was no evidence that any different process was used to produce the articles shipped to Export.

Thus it cannot be said that the district court erred in determining that the invention set forth in claim 1 of '566 patent was known or used by others under §102(a), as evidenced by Gore's operation of the 401 machine before Dr. Gore's asserted date of that invention.

In view of our affirmance of the judgment reached on claim 1 under 102(a), we need not discuss other asserted grounds of invalidity of claim 1. There was, however, no evidence whatever that the inventions set forth in other claims, of either the '566 or the '390 patent, were known or used by others as a result of Gore's operation of the 401 machine before late October 1969.

## (ii) §102(b) and the Cropper Machine

In 1966 John W. Cropper (Cropper) of New Zealand developed and constructed a machine for producing stretched and unstretched PTFE thread seal tape. In 1967, Cropper sent a letter to a company in Massachusetts, offering to sell his machine, describing its operation, and enclosing a photo. Nothing came of that letter. There is no evidence and no finding that the present inventions thereby became known or used in this country.

In 1968, Cropper sold his machine to Budd, which at some point thereafter used it to produce and sell PTFE thread seal tape. The sales agreement between Cropper and Budd provided:

## ARTICLE "E" - PROTECTION OF TRADE SECRETS Etc.

1. BUDD agrees that while this agreement is in force it will not reproduce any copies of the said apparatus without the express written permission of Cropper nor will it divulge to any person or persons other than its own employees or employees of its affiliated corporations any of the said known-how or any details whatsoever relating to the apparatus.

2. BUDD agrees to take all proper steps to ensure that its employees observe the terms of Article "E" 1 and further agrees that whenever it is proper to do so it will take legal action in a Court of competent jurisdiction to enforce any one or more of the legal or equitable remedies available to a trade secret plaintiff.

Budd told its employees the Cropper machine was confidential and required them to sign confidentiality agreements. Budd otherwise treated the Cropper machine like its other manufacturing equipment.

A former Budd employee said Budd made no effort to keep the secret. That Budd did not keep the machine hidden from employees legally bound to keep their knowledge confidential does not evidence a failure to maintain the secret. Similarly, that du Pont employees were shown the machine to see if they could help increase its speed does not itself establish a breach of the secrecy agreement. There is no evidence of when that viewing occurred. There is no evidence that a viewer of the machine could thereby learn anything of which process, among all possible processes, the machine is being used to practice. As Cropper testified, looking at the machine in operation does not reveal whether it is stretching, and if so, at what speed. Nor does looking disclose whether the crystallinity and temperature elements of the invention set

forth in the claims are involved. There is no evidence that Budd's secret use of the Cropper machine made knowledge of the claimed process accessible to the public.

The district court held all claims of the '566 patent invalid under 102(b), supra, note 3, because "the invention" was "in public use [and] on sale" by Budd more than one year before Gore's application for patent. Beyond a failure to consider each of the claims independently, 35 U.S.C. §282; *Altoona Public Theatres, Inc. v. American Tri-Ergon Corp.*, 294 U.S. 477, 487, 24 USPQ 308 (1935), and a failure of proof that the claimed inventions as a whole were practiced by Budd before the critical May 21, 1969 date, it was error to hold that Budd's activity with the Cropper machine, as above indicated, was a "public" use of the processes claimed in the '566 patent, that activity having been secret, not public.

Assuming, arguendo, that Budd sold tape produced on the Cropper machine before October 1969, and that that tape was made by a process set forth in a claim of the '566 patent, the issue under §102(b) is whether that sale would defeat Dr. Gore's right to a patent on the process inventions set forth in the claims.

[8] If Budd offered and sold anything, it was only tape, not whatever process was used in producing it. Neither party contends, and there was no evidence, that the public could learn the claimed process by examining the tape. If Budd and Cropper commercialized the tape, that could result in a forfeiture of a patent granted them for their process on an application filed by them more than a year later. *D.L. Auld Co. v. Chroma Graphics Corp.*, No. 83-585, slip op. at 5-6 (Fed. Cir. Aug. 15, 1983); See *Metalizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516, 68 USPQ 54 (2d Cir. 1946). There is no reason or statutory basis, however, on which Budd's and Cropper's secret commercialization of a process, if established, could be held a bar to the grant of a patent to Gore on that process.

[9,10] Early public disclosure is a linchpin of the patent system. As between a prior inventor who benefits from a process by selling its product but suppresses, conceals, or otherwise keeps the process from the public, and a later inventor who promptly files a patent application from which the public will gain a disclosure of the process, the law favors the latter. See *Horwath v. Lee*, 564 F.2d 948, 195 USPQ 701 (CCPA 1977). The district court therefore erred as a matter of law in applying the statute and in its determination that Budd's secret use of the Cropper machine and sale of tape rendered all process

claims of the '566 patent invalid under §102(b).

(iii) §103

In considering claims 1, 3, 17, and 19 of the '566 patent, the district court recognized that analysis of the obviousness issue under §103 requires determination of the scope and content of the prior art, the differences between the prior art and the claims at issue, and the level of ordinary skill in the pertinent art. *Graham v. John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966).

[11,12,13] In its consideration of the prior art, however, the district court erred in not taking into account the import of the markedly different behavior of PTFE from that of conventional thermoplastic polymers clearly established and undisputed on the record, and in thus disregarding the unpredictability and unique nature of the unsintered PTFE to which the claimed inventions relate. *In re Whiton*, 420 F.2d 1082, 164 USPQ 455 (CCPA 1970); in considering claims in less than their entirety, *Schenck*, supra; and in considering the references in less than their entirety, i.e., in disregarding disclosures in the references that diverge from and teach away from the invention at hand. *In re Kuderma*, 426 F.2d 385, 165 USPQ 575 (CCPA 1970).

Invalidity of claim 1 under §102(a) having been determined, it is unnecessary to discuss in detail the applicability of §103 to that claim. If claim 1 had not been held anticipated under §102(a) in light of operation of the 401 machine, it is clear from the discussion here that claim 1 could not properly have been held invalid under §103.

Claim 3 depends from and thus incorporates claim 1 but specifies a rate of stretch of 100% per second. Claim 17 also depends from claim 1 and specifies an amount of stretch of about twice the original length. Claim 19 depends from claim 17 but specifies an amount of stretch of about five times the original length.

U.S. patent 2,983,961 to Tiuerton, Volume 13 of the *Encyclopedia of Polymer Science and Technology* (1970), the Sumitomo patent, and witnesses for both parties, establish that teachings related to conventional thermoplastic polymers are inapplicable to PTFE.

Articles by Dogliotti and Yelland, *Effect of Strain Rate on the Viscoelastic Properties of High Polymeric Fibrous Materials*, 4 *High Speed Testing* 211 (1964) and Robinson and Graham, *Methods of Characterization of Polymeric Materials by High Speed Testing Techniques*, 5 *High Speed Testing* 261

(1965), teach that conventional plastics and sintered PTFE can be stretched further if stretched slowly. Dr. Gore demonstrated at trial and at oral argument before us that an attempt to stretch highly crystalline, unsintered PTFE slowly results in breakage, and that rapid stretching produces a greatly lengthened rod of soft, flexible material.

The '566 patent contains an example of stretching an article to 16 times its length. Smith and the '915 patent teach that PTFE could not be stretched beyond four times its length without heating it to above its crystalline melt temperature, a step avoided by Dr. Gore and as set forth in the claims.

Sumitomo teaches that there is a length limit to stretching unsintered PTFE, and does not suggest what that limit might be. Markwood, U.S. patent 3,208,100 to Nash (Nash), and U.S. patent 2,823,421 to Scarlett (Scarlett) teach that *non-PTFE* thermoplastics can be stretched rapidly and to extended lengths, and also teach reduction, elimination, or avoidance of crystallinity before stretching.

The disclosure in the Smith and '915 patents that a PTFE article may be stretched to as much as four times its length encompasses the step of stretching to twice its length set forth in claim 17 and establishes that such step would have been obvious.

[14] Claims 3 and 19 must be considered individually and separately. 35 U.S.C. §282. Nowhere, in any of the references, is it taught or suggested that highly crystalline, unsintered PTFE could be stretched at a rate of about 100% per second as required by asserted claim 3. Nor is it anywhere suggested that by rapid stretching a PTFE article be stretched to more than five times its original length as required by asserted claim 19. On the contrary, the art as a whole teaches the other way.

[15] In concluding that obviousness was established by the teachings in various pairs of references, the district court lost sight of the principle that there must have been something present in those teachings to suggest to one skilled in the art that the claimed invention before the court would have been obvious. *In re Bergel*, 292 F.2d 955, 956-57, 130 USPQ 206, 208 (CCPA 1961); *In re Sponnoble*, 405 F.2d 578, 585, 160 USPQ 237, 244 (CCPA 1969).

The court's pairing of Sumitomo and Markwood disregarded, as above indicated, the undisputed evidence that the unsintered PTFE of Sumitomo does not respond to the conventional plastics processing of Markwood and the art recognition of that fact. *Whiton*, supra, 420 F.2d at 1085, 164 USPQ at 457.

In evaluating claim 19, for example, the pairing disregarded Sumitomo's limited

length of stretch teaching. In evaluating claim 3, the court recognized that Sumitomo made no mention of rate of stretch. Looking to Markwood to supply that teaching disregarded not only the conventional plastics-unsintered PTFE distinction but also the clear divergence of Markwood's teaching that crystallinity must be reduced or avoided from the presence of "highly crystalline" in all claims of the '566 patent.

Similarly, and for many of the same reasons, the pairing of Markwood's and Smith's teachings was an inappropriate basis for concluding that the processes set forth in claims 3 and 19 would have been obvious. As above indicated, Markwood's rapid stretching of conventional plastic polypropylene with reduced crystallinity would not suggest rapid stretching of highly crystalline PTFE, in light of teachings in the art that PTFE should be stretched slowly. The Smith patent is owned by du Pont, where Dr. Gore's process invention was considered to have produced a "remarkable new material." That circumstance is not surprising, for Smith, though dealing with PTFE, says not a word about any rate of stretch.

Lastly, the pairing of Sumitomo and the '915 patent suffers from the same shortcomings. The pairing resulted from a hypothetical set forth in Garlock's post trial brief, and was based on no testimony or other evidence in the record. In respect to claim 3, neither reference mentions rate of stretch or suggests its importance. In respect of claim 19 both references point away from the claimed invention in their limited length-of-stretch teachings. The '915 patent states: "the 65 percent expanded material could be expanded a second time for an additional 65 percent expansion or a total length increase ratio of 1:2.72 [less than three times the original length]. However, great care was necessary to obtain a uniformly expanded material at these very great expansion ratios." Thus the '915 patent suggests that the amount of stretch of 500% set forth in claim 19 (more than five times the original length) is not possible.

As indicated, Sumitomo and Smith are totally silent respecting the rate of stretch, and there is simply no teaching in the art that would suggest to one of ordinary skill that Markwood's fast stretching of other thermoplastics could or should be employed in the process of treating PTFE taught by either Sumitomo or Smith. Indeed, Smith not only says nothing about rate of stretch, its preferred teaching is away from other elements of the inventions set forth in claims 3 and 19. Smith discloses that stretching should be done after the PTFE is heated above its crystalline

melting point and with decreased crystallinity. Smith teaches:

Below about 300°C it is *not possible* to draw more than about 4X [times] and while such draw ratios can be attained around 300°C and below the polymer's crystalline melting point with resultant orientation and improved properties it is preferred to use temperatures at or above the polymer's crystalline melting point. (Emphasis added).

Nash teaches that the film should be plasticized, i.e., made more viscous, before stretching. Contrary to that teaching, Dr. Gore did not reduce crystallinity before increasing the rate of stretch, but maintained the unsintered PTFE "highly crystalline" while stretching at a 100% per second rate and to more than five times, as set forth respectively in claims 3 and 19.

[16] On the entire record and in view of all the references, each in its entirety, it is clear that a person of ordinary skill confronted with a PTFE tape breakage problem would have either slowed the rate of stretching or increased the temperature to decrease the crystallinity. Dr. Gore did neither. He proceeded contrary to the accepted wisdom of the prior art by dramatically increasing the rate and length of stretch *and* retaining crystallinity. That fact is strong evidence of nonobviousness. *United States v. Adams*, 383 U.S. 39 (1966).

Having learned the details of Dr. Gore's invention, the district court found it within the skill of the art to stretch other material rapidly (Markwood); to stretch PTFE to increase porosity (Sumitomo); and to stretch at high temperatures (Smith). The result is that the claims were used as a frame, and individual, naked parts of separate prior art references were employed as a mosaic to recreate a facsimile of the claimed invention. At no point did the district court, nor does Garlock, explain why that mosaic would have been obvious to one skilled in the art in 1969, or what there was in the prior art that would have caused those skilled in the art to disregard the teachings there found against making just such a mosaic. On the contrary, the references and the uncontested testimony, as above indicated, established that PTFE is *sui generis*. It is not surprising, therefore, that, unlike the situation in *Stratoflex, Inc. v. Aeroquip Corp.*, 218 USPQ 871 (Fed. Cir. 1983), there was no testimony and no finding that one skilled in the art would transfer conventional thermoplastic processes to those for unsintered PTFE, or would have been able to predict what would happen if they did.

[17] To imbue one of ordinary skill in the art with knowledge of the invention in suit,

when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher.

[18] It is difficult but necessary that the decisionmaker forget what he or she has been taught at trial about the claimed invention and cast the mind back to the time the invention was made (often as here many years), to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art. Had that been here done the inventions set forth in the claims 3 and 19 of the '566 patent could only have been held non-obvious to those skilled in the art at the time those claimed inventions were made.

[19] Error in visualizing the burden of proof on obviousness may have contributed to the court's application here of the prior art. Adopting the phrase from earlier precedents, the court said "the presumption [of validity] is weakened greatly where the Patent Office has failed to consider pertinent prior art." That is not the law of established precedent in this court. *SSIH Equipment S.A. v. ITC*, 218 USPQ 678, 687 (Fed. Cir. 1983); *Solder Removal Co. v. ITC*, 582 F.2d 628, 633, 199 USPQ 129, 133, n. 9 (CCPA 1978). The presumption has no separate evidentiary value. It cautions the decisionmaker against a rush to conclude invalidity. Submission of additional art that is merely "pertinent" does not dispel that caution. It is difficult to imagine a patent law suit in which an accused infringer is unable to add some new "pertinent" art. The inescapable burden of persuasion on one who would prove invalidity, however, remains throughout the trial. 35 U.S.C. §282.

[20] The burden of proving invalidity may of course be facilitated by prior art that is more pertinent than that considered by the PTO. That did not happen here. In the present case, Sumitomo, Smith, and the '915 patent were among references considered by the PTO. Other references referred to as not considered were merely cumulative, disclosing nothing not disclosed in references that were considered by the PTO. The Canadian counterpart of Nash was considered by the PTO. The relevant disclosures of Markwood appear in Sandiford patent 3,544,671 and Paratheon patent 3,637,906, both considered by the PTO. The Russian Author's Certificate 240,997, assuming its status as prior art and whatever the material with which it dealt, contributed nothing beyond the teachings of the '915 patent considered by the PTO.

[21] As discussed more fully below, the district court erred in specifically declining to

consider the objective evidence of nonobviousness. In re Sernaker, 702 F.2d 989, 996, 217 USPQ 1, 7 (Fed. Cir. 1983). That evidence can often serve as insurance against the insidious attraction of the siren hindsight when confronted with a difficult task of evaluating the prior art. Though the prior art evidence here pointed more in the direction of nonobviousness than obviousness, the objective evidence may tend, as it did in Sernaker, supra, to reassure the decisionmaker.

In sum, the district court erred as a matter of law on this record in concluding that Garlock had met its burden of proving that the inventions of claims 3 and 19 of the '566 patent would have been obvious.

#### (b) '390 patent

##### (i) §102

The district court found product claims 1, 9, 12, 14, 18 and 43 inherently anticipated because it found that the microstructure of nodes interconnected by fibrils is an inherent characteristic of paste-extruded PTFE products resulting from the process disclosed in Smith. The court found the first four of those claims and claim 43, plus claims 35, 36, 67 and 77 inherently anticipated because high strength PTFE products are inherent in the examples of Sumitomo.

The teachings of Smith include neither a disclosure nor a suggestion of "porous" products having a "microstructure characterized by nodes interconnected by fibrils" as required by the claims found to have been anticipated by Smith.

The teachings of Sumitomo do not include a disclosure of products having "a matrix tensile strength \*\*\* above about 7,300 psi" as required by the claims found to have been anticipated by Sumitomo.

[22] Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration. *Soundscriber Corp. v. U.S.*, 360 F.2d 954, 960, 148 USPQ 298, 301, adopted, 149 USPQ 640 (Ct. Cl. 1966). Neither Smith nor Sumitomo disclose an invention set forth in any claim of the '390 patent.

The incongruity in findings that the different processes of Smith and Sumitomo each inherently produced identical products is striking.

Garlock attempted with expert testimony to overcome the prior art shortcomings as proof of anticipation. Gore rebutted with its own expert testimony. It is unnecessary, however, to resolve apparent conflicts in the divergent testimony, much if not all of which took

the form of pure unsupported assertion. No inter partes tests in which the Smith and Sumitomo processes were conducted are of record. No products of those processes were placed in evidence, and there was, of course, no analysis of any such evidentiary products.

Nor is it necessary to evaluate the inappropriate disparagement in Garlock's brief of Dr. Sperati as a "friend" of Gore.

[23] Given the unique nature of unsintered PTFE, we are not persuaded that the "effect" of the processes disclosed in Smith and Sumitomo, an "effect" undisclosed in those patents, would be always to inherently produce or be seen always to produce products meeting all of the claim limitations. Anticipation of inventions set forth in product claims cannot be predicated on mere conjecture respecting the characteristics of products that might result from the practice of processes disclosed in references. In *re Felton*, 484 F.2d 495, 500, 179 USPQ 295, 298 (CCPA 1973). It is clear that the teachings of neither Smith nor Sumitomo place the products claimed in the '390 patent in possession of the public.

The teachings of Smith and Sumitomo are so unacceptably vague concerning characteristics of products produced by their respective processes as not to support an anticipation rejection. That fact is confirmed by the PTO's having fully considered those references and by its having issued the '390 patent over them.

[24] Garlock's assertion that it employs a process covered by the Smith patent, if true, is irrelevant. The '390 patent was allowed over Smith as a reference. Assuming Smith is a dominating patent, the rule of law is clear that an accused infringer's employment of the process of a dominating patent does not render that employment an anticipation of an invention described and claimed in an improvement patent. As indicated, there is no present record basis for finding that the Smith process in itself necessarily and inherently results in the products, each considered in its entirety, in the claims of the '390 patent. The testimony of Garlock's expert about *ex parte* tests, the records of which he destroyed before trial, cannot serve as such a basis. The effusive praise of Dr. Gore's claimed products by the owner of the Smith patented process would appear, on the contrary, to confirm the action of the PTO in issuing the '390 patent.

Garlock has not met its burden of showing that claims 1, 9, 12, 14, 18, and 43 are anticipated by Smith or that claims 1, 9, 12, 14, 35, 36, 43, 67, and 77 are anticipated by Sumitomo.

(ii) §103

[25] The scope and content of the prior art and level of ordinary skill, discussed above in relation to the '566 patent, would be the same for the '390 patent. The district court did not, however, nor does Garlock, apply the Graham criteria, *supra*, to the '390 claims, apparently assuming that the claimed products, having been found inherent in the processes of Sumitomo and Smith, would have been obvious in view of those references. If so, that was error. Inherency and obviousness are distinct concepts. In *re Spormann*, 363 F.2d 444, 448, 150 USPQ 449, 452 (CCPA 1966).

In discussing inherency the district court did recognize differences between Smith's disclosure and the inventions set forth in claims 1, 9, 12, 14, 18, and 43, i.e., the absence from Smith of a description of the products of Smith's process as porous and the absence from Smith of a disclosure that those products have a microstructure characterized by nodes interconnected by fibrils.

Similarly, a difference between Sumitomo's disclosure and the inventions set forth in claims 1, 9, 12, 14, 35, 36, 43, 67, and 77 was recognized in the absence from Sumitomo of a quantification of the matrix tensile strengths of the products of Sumitomo's process. The district court also discussed differences between the dependent claims and the prior art. Because we conclude that the independent claims of the '390 patent are patentable over the art of record, we need not discuss the dependent claims.

[26] Having determined that the invention would have been obvious in view of the process of either Smith or Sumitomo, the district court did not discuss the strong showing of objective evidence of nonobviousness here present, saying with respect to one part of such evidence, "no amount of commercial success can save it." That approach was error. All evidence bearing on the issue of obviousness, as with any other issue raised in the conduct of the judicial process, must be considered and evaluated *before* the required legal conclusion is reached. *Stratoflex*, *supra*, 218 USPQ at 879.

[27] The objective evidence of nonobviousness, i.e., the "indicia" of Graham, *supra*, may in a given case be entitled to more weight or less, depending on its nature and its relationship to the merits of the invention. It may be the most pertinent, probative, and revealing evidence available to aid in reaching a conclusion on the obvious/nonobvious issue. It should when present always be considered as an integral part of the analysis.

Gore's fabric laminates, for example, as set forth in claims 36 and 77, satisfied a long-felt

need for a material having the contradictory properties of being simultaneously breathable (allowing water vapor or perspiration to pass) and waterproof. The record establishes that such a material had long been sought by makers of rainwear and outerwear, and by the U.S. Army as well. That Gore's fabric laminates filled that need is attested by the rise in their annual dollar sales from zero to seven million in the first five years of their availability.

Gore's PTFE tubes for replacement of human arteries and veins, also satisfied a long-felt need. The uncontradicted evidence establishes that Gore's PTFE tubes hold blood without leaking, need not be pre-clotted with the patient's blood, are chemically inert, and, being breathable, are less likely to cause an air embolism. The value and uniqueness of those four properties make Gore's PTFE tubes, as described in unchallenged testimony, "the most important synthetic material presently existing" in vascular surgery, and, along with other evidence in the record, reflect the intended working of the patent system.

As discussed above, current annual sales of over sixty million dollars are attributable to the merits of the products claimed in the '390 patent. Considering the long-felt need for those products and the obvious commercial advantage to be gained by meeting that need, it is reasonable to conclude that the claimed products of the '390 patent would not have been obvious to persons of ordinary skill in the art at the time the claimed inventions were made.

[28] As above indicated, the praise which greeted the products claimed in the '390 patent from PTFE suppliers, including the owner of the Smith patent, is further objective evidence of nonobviousness.

[29] Garlock's appeal argument that the '390 claims are invalid because the recited minimum matrix tensile strengths are not "critical" is without merit. A claim to a new product is not legally required to include critical limitations. In *re Miller*, 441 F.2d 689, 696, 169 USPQ 597, 602 (CCPA 1971). The '390 claims are not drawn to optimization of ingredients or ranges within broad prior art teachings, but to new porous PTFE products of particular characteristics.

In sum, and in view of the difficulty of working with unsintered PTFE and its unpredictable response to various processing techniques, the vagueness of Smith and Sumitomo concerning the products produced by those processes, the filling of at least two long-felt needs and the commercial success described above, we conclude that the inventions set forth in claims 1, 9, 12, 14, 18, 35, 36, 43, 67, and 77 of the '390 patent would

not have been obvious to those skilled in the art at the time those inventions were made.

*(c) §112 and the '566 and '390 patents*

The patents in suit resulted from a single application and thus have substantially identical specifications. The holding of invalidity on the basis of §112 is common to both patents.

The district court found that the patents did not disclose sufficient information to enable a person of ordinary skill in the art to make and use the invention, as required by §112, first paragraph, and that certain claim language was indefinite, presumably in light of §112, second paragraph, because: (1) there was no definition in the specification of "stretch rate," different formulae for computing stretch rate having been developed and presented at trial; (2) there was no way taught in the specification to calculate the minimum rate of stretch above 35°C; (3) the phrase "matrix tensile strength" is indefinite; and (4) the phrase "specific gravity of the solid polymer" is indefinite.

[30] The findings rest on a misinterpretation of §112, its function and purpose. The district court considered whether certain terms would have been enabling to the public and looked to formula developments and publications occurring well after Dr. Gore's filing date in reaching its conclusions under §112. Patents, however, are written to enable those skilled in the art to practice the invention, not the public. In *re Storrs*, 245 F.2d 474, 478, 114 USPQ 293, 296-97 (CCPA 1957), and §112 speaks as of the application filing date, not as of the time of trial. In *re Mott*, 539 F.2d 1291, 1296, 190 USPQ 536, 541 (CCPA 1976). There was no evidence and no finding that those skilled in the art would have found the specification non-enabling or the claim language indefinite on May 21, 1970, when the application which resulted in issuance of Dr. Gore's patents was filed. Indeed, the expert quoted by the district court and whose testimony was primarily relied upon respecting formulae, was still in school at that time.

There is uncontradicted evidence in the record that at the time the application was filed "stretch rate" meant to those skilled in the art the percent of stretch divided by the time of stretching, and that the latter was measurable, for example, with a stopwatch. Concern for the absence from the specification of a formula for calculating stretch rate is therefore misplaced, and the post-filing date development of varying formulae, including Dr. Gore's later addition of a formula in his corresponding Japanese patent, is irrelevant.

[31] Section 112 requires that the inventor set forth the best mode of practicing the invention known to him at the time the application was filed. Calculating stretch rate at that time was accomplished by actually measuring the time required to stretch the PTFE material. That was the only mode then used by the inventor, and it worked. The record establishes that calculation by that mode would have been employed by those of ordinary skill in the art at the time the application was filed. As indicated, Dr. Gore's disclosure must be examined for §112 compliance in light of knowledge extant in the art on his application filing date.

[32] The district court, though discussing enablement, spoke also of indefiniteness of "stretch rate," a matter having to do with §112, second paragraph, and relevant in assessment of infringement. The use of "stretching \* \* \* at a rate exceeding about 10% per second" in the claims is not indefinite. Infringement is clearly assessable through use of a stopwatch. No witness said that could not be done. As above indicated, subsequently developed and therefore irrelevant formulae cannot be used to render non-enabling or indefinite that which was enabling and definite at the time the application was filed.

[33] Similarly, absence from the specification of a method for calculating the minimum rate of stretch above 35°C does not render the specification non-enabling. The specification discloses that "[t]he lower limit of expansion rates interact with temperature in a roughly logarithmic fashion, being much higher at higher temperatures." Calculation of minimum stretch rate above 35°C is nowhere in the claims, and it is the *claimed* invention for which enablement is required. The claims require stretching at a rate greater than 10% per second at temperatures between 35°C and the crystalline melt point of unsintered PTFE. That the minimum rate of stretch may increase with temperature does not render non-enabling Dr. Gore's specification, particularly in the absence of convincing evidence that those skilled in the art would have found it non-enabling at the time the application was filed.

[34] The district court invalidated both patents for indefiniteness because of its view that some "trial and error" would be needed to determine the "lower limits" of stretch rate above 10% per second at various temperatures above 35°C. That was error. Assuming some experimentation were needed, a patent is not invalid because of a need for experimentation. *Minerals Separation, Ltd. v. Hyde*, 242 U.S. 261, 270-71 (1916). A patent is invalid only when those skilled in the art are required to

engage in *undue* experimentation to practice the invention. *In re Angstadt*, 537 F.2d 498, 503-04, 190 USPQ 214, 218 (CCPA 1976). There was no evidence and the court made no finding that undue experimentation was required.

[35] Moreover, the finding here rested on confusion of the role of the specification with that of the claims. The court found that the specification's failure to state the lower limit of stretch rate (albeit above 10% per second) at each degree of temperature above 35°C (a requirement for at least hundreds of entries in the specification) did not "distinguish processes performed above the 'lower limit' from those performed below the 'lower limit'." The claims of the '390 patent say nothing of processes and lower limits. Distinguishing what infringes from what doesn't is the role of the claims, not of the specification. It is clear that the specification is enabling. *In re Storrs*, *supra*, and that the claims of both patents are precise within the requirements of the law. *In re Moore*, 439 F.2d 1232, 169 USPQ 236 (CCPA 1971).

[36] The finding that "matrix tensile strength" is indefinite, like the other findings under §112, appears to rest on a confusion concerning the roles of the claims and the specification. While finding "matrix tensile strength" in the claims indefinite, the district court at the same time recognized that the specification itself disclosed how to compute matrix tensile strength, in stating "to compute matrix tensile strength of a porous specimen, one divides the maximum force required to break the sample by the cross sectional area of the porous sample, and then multiplies this quantity by the ratio of the specific gravity of the solid polymer divided by the specific gravity of the porous specimen." Further, the specification provided the actual matrix tensile strength in several examples. It is well settled that a patent applicant may be his own lexicographer. In light of the disclosure of its calculation in the specification, we cannot agree that "matrix tensile strength" is either indefinite or non-enabling.

Nor does absence from the specification of a definition for "specific gravity of the solid polymer," a part of the computation of matrix tensile strength, render that computation indefinite. It is undisputed that in the many examples in the application the specific gravity values used for unsintered and sintered PTFE were 2.3 and 2.2, respectively. There was no testimony that those values were not known to persons of ordinary skill in the art or could not be calculated or measured. There is simply no support for the conclusion that "specific gravity of the solid polymer" is indefinite or that absence of its definition ren-

is the specification non-enabling. See *In re Weithelm*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976).

We conclude that Garlock has failed to prove that at the time the application was filed, the specification was not enabling or that the claims were indefinite within the meaning of §112.

### (2) Fraud

[37] Fraud must be shown by clear and convincing evidence. *Norton v. Curtiss*, 433 F.2d 779, 797, 167 USPQ 532, 546-47 (CCPA 1970).

The state of mind of the one making the representations is probably the most important of the elements to be considered in determining the existence of "fraud." \* \* \* Good faith and subjective intent, while they are to be considered, should not necessarily be made controlling. Under ordinary circumstances, the fact of misrepresentation coupled with proof that the party making it had knowledge of its falsity is enough to warrant drawing the inference that there was a fraudulent intent. Where public policy demands a complete and accurate disclosure it may suffice to show nothing more than that the misrepresentations were made in an atmosphere of gross negligence as to their truth. [emphasis in original].

*Norton*, 433 F.2d at 795-96; 167 USPQ at 545; see, *Miller*, *Fraud on the PTO*, 58 JPOS 271 (1976).

Garlock alleges fraud in Gore's representations that stretching PTFE tape at a rate greater than 10% per second was novel and that it produces a physical phenomenon. The district court found the evidence insufficient to establish that Gore had a specific intent to defraud the PTO. No basis exists for our overturning that finding. Accordingly, we agree with the district court that Garlock has failed to sustain its heavy burden of proving, by clear and convincing evidence, sufficient facts from which fraudulent intent can be inferred.

Garlock points to a September 4, 1975, Gore affidavit filed in the PTO that stated:

2. Prior to my invention disclosed in the captioned patent application, during production of expanded PTFE products by W. L. Gore & Associates, Inc., the rate of stretching was neither measured nor controlled and to my knowledge did not involve stretching of unsintered PTFE at a rate exceeding about 10% per second. (emphasis in original)

No finding of the district court and no evidence of record establishes that that state-

ment was made in reckless disregard of facts from which an intent to defraud may be inferred.

The district court's finding in 1982 that the 401 machine inherently stretched tape at some time in 1969 at a rate more than 10% per second, does not establish that Dr. Gore was aware of that fact in 1975, nor does it make untrue his statement that to his knowledge that had not been the rate of stretch employed. Nor does the district court's finding conflict with Dr. Gore's statement that the rate of stretching was neither measured nor controlled in the Gore shop before his invention of the claimed process as a whole.

Nor does the evidence of isolated statements support Garlock's contention that Dr. Gore attempted to convince the PTO that a physical phenomenon always existed in which stretching at a rate greater than 10% per second always produced a matrix tensile strength greater than 7300 psi. On the contrary, Dr. Gore set forth in his specification examples indicating that some samples broke, ruptured, or disintegrated.

### (3) Attorney's Fees

The district court did not abuse its discretion in denying Garlock its request for attorney fees.

### Infringement

[38] Where, as here, an appellate court reverses a holding of invalidity, and remand is ordered for trial of the factual issue of infringement, an inefficient use of judicial resources results if the second judgment is appealed. The better practice would therefore be for the district court to decide both the validity and infringement issues when both are contested at the trial, enabling the conduct of a single appeal and disposition of the entire case in a single appellate opinion.

Resolution of the infringement issue at trial may also overlap with resolution of the validity issue, where, for example, the claimed invention was or was not copied by the validity challenger, or the challenger substituted the claimed invention for freely available prior art processes or products, *Eibel*, supra, 261 U.S. at 56, or an assertion of nonenablement may conflict with the ease with which the accused infringer may be shown to have practiced the invention as taught in the patent. *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 61 (1923).

[39] The district court having declined to decide the infringement issue, Gore suggests that the record here is sufficient to warrant

our deciding it now. With reluctance in view of the length and bitter nature of the present litigation, we decline the suggestion. In so doing, we imply nothing of our view on the issue. Nor do we intend any implication that the district court could not itself determine the infringement issue on the present record. Infringement of particular claims of two patents was asserted. None of those claims has been finally held invalid. Assuming their continued assertion, infringement must be decided with respect to each asserted claim as a separate entity. *Altoona, supra*, 294 U.S. at 487. Those factual determinations should be made in the first instance by the district court.

#### Decision

The holdings of invalidity of claim 1 of the '566 patent under §102(a) and of claim 17 of the '566 patent under §103, the determination that Gore did not commit fraud on the PTO, and the denial of attorney fees, are affirmed; the holdings that all claims of the '566 patent are invalid under §102(b), that claims 3 and 19 of the '566 patent are invalid under §103, and that all claims of the '566 patent are invalid under §112, are reversed. The holdings that claims 1, 9, 12, 14, 18, 35, 36, 43, 67, and 77 of the '390 patent are invalid under §§102 and 103, and that all claims of the '390 patent are invalid under §112, are reversed. The case is remanded for determination of the infringement issue.

*Affirmed in part, reversed in part, and remanded.*

#### Appendix

Claims of the '566 patent discussed at trial:

1. A process for the production of a porous article of manufacture of a polymer of tetrafluoroethylene which process comprises expanding a shaped article consisting essentially of highly crystalline poly (tetrafluoroethylene) made by a paste-forming extrusion technique, after removal of lubricant, by stretching said unsintered shaped article at a rate exceeding about 10% per second and maintaining said shaped article at a temperature between about 35°C. and the crystalline melt point of said tetrafluoroethylene polymer during said stretching.

3. The process of claim 1 in which the rate of stretch is about 100% per second.

17. The process of claim 1 in which the shaped article is expanded such that its final length in the direction of expansion is greater than about twice the original length.

19. The process of claim 17 in which said final length is greater than about five times the original length.

Claims of the '390 patent discussed at trial:

1. A porous material consisting essentially of highly crystalline polytetrafluoroethylene polymer, which material has a microstructure characterized by nodes interconnected by fibrils and has a matrix tensile strength in at least one direction above about 73,000 psi.

9. A porous material consisting essentially of polytetrafluoroethylene polymer, which material has a microstructure characterized by nodes interconnected by fibrils and has a matrix tensile strength in at least one direction above 9290 psi, which material has been heated to a temperature above the crystalline melt point of said polymer and has a crystallinity below about 95%.

12. A porous material in accordance with claim 9 which is in the form of a shaped article.

14. A product in accordance with claim 12 which is in the form of a film.

18. A product in accordance with claim 12 which is in the form of continuous filaments.

35. A laminated structure comprising (a) a first shaped article formed of a porous material made of a tetrafluoroethylene polymer, which material has a microstructure characterized by nodes interconnected by fibrils and has a matrix tensile strength in at least one direction above about 7,300 psi, and (b) a second shaped article bonded to said first shaped article.

36. The structure of claim 35 in which said first shaped article is formed of a porous material which has a matrix tensile strength in at least one direction of at least 9290 psi, and has a crystallinity below about 95%.

43. A porous material made of a tetrafluoroethylene polymer, which material has a microstructure characterized by nodes interconnected by fibrils, which material (a) has a matrix tensile strength in at least one direction above about 9290 psi, (b) has been heated to a temperature above 327°C. and has a crystallinity below about 95%, and (c) has a dielectric constant of 1.2-1.8.

67. An impregnated structure comprising

(a) a shaped article formed of a porous material made of a tetrafluoroethylene polymer which material has a microstructure characterized by nodes interconnected by fibrils and a matrix tensile strength in at least one direction above about 9290 psi, and

(b) a polymer impregnated within the pores of the said shaped article.

77. The structure of claim 35 in which the first shaped article is a sheet having pores that will pass a gas but will not pass liquid water.

Davis, Circuit Judge, concurring in the result in part and dissenting in part.

I concur in the result on (1) the validity of the '390 patent under §§ 102-103; (2) the validity of the '390 patent under §112; (3) the invalidity of claims 1 and 17 of the '566 patent; (4) lack of fraud on the Patent and Trademark Office; and (5) denial of attorneys' fees. I disagree and dissent as to the validity of claims 3 and 19 of the '566 patent.

1. The process invention embodied in claim 1 of the '566 patent was known, through use of the 401 machine in the Gore shop, well before the "invention date" (claimed by Robert Gore, the inventor) of October 1969.<sup>1</sup> As such, the claimed invention was invalid on at least three grounds: (i) it was anticipated and therefore would have been obvious (under 35 U.S.C. §103) at the time of the claimed invention date; (ii) the invention was "in public use" by the Gore shop (under 35 U.S.C. §102(b)) more than one year prior to the patent application (i.e., prior to May 21, 1969); and (iii) the invention (made by Robert Gore) was known to and used "by others in this country" (35 U.S.C. §102(a)) before the claimed invention date of October 1969, i.e. the invention was used by Wilbert Gore and others in the Gore shop before the October date.<sup>2</sup>

The critically important aspect of the invention of the '566 patent is the stretching of PTFE at a rate above 10% per second.<sup>3</sup> Robert Gore testified that he conceived this invention no earlier than October 1969 (and we have the right to take him at his word),<sup>4</sup> but the facts found by the District Court plainly show that the Gore shop was in fact practicing that invention considerably earlier.

The District Court found that in the 401 machine the distance between the stretch rollers controls the rate of stretch; a shorter distance results in a higher rate of stretch; for the process described in the '915 patent to be practiced with a rate of stretch below 10% per second, the distance between the stretch rollers would have to be greater than five feet; if the distance is less than four feet, the rate of stretch is greater than 10% per second; the machine drawings used to construct the 401 machine indicate that the distance between the stretch rollers was eight inches; a Gore employee testified that "I am reasonably sure that no effective [stretch] rolls in question would have been more than three feet simply because of the nature and size of the equipment" and that he did not remember any stretching more than three feet; another Gore employee testified that the distance between the rollers was "a maximum of 18 inches" (emphasis added); a document prepared by the same employee (an engineer) on June 10, 1969 reports that the stretch span was 8 inches; the 401 machine was the only stretching machine used by the Gore company; and the 401 machine was never substantially changed before October 1969. All this adds up to the fact that the 401 machine was at all relevant times operated with a stretch of less than four feet.<sup>5</sup> There is no question that the machine was so operated before October 1969 (the District Court found that sales of tape made by the 401 machine were proposed in August 1969).

I can accept Robert Gore's affidavit (to the PTO) that there was no stretching in the Gore shop at a rate exceeding about 10% per second prior to "my invention disclosed in the captioned patent application" (emphasis added)<sup>6</sup> only because that declaration was expressly qualified by the phrase "to my knowledge" (emphasis added). The District Court specifically found no specific intent by Robert Gore to defraud and, on this record, we

<sup>1</sup> The Gores (Robert and Wilbert) testified at trial that the distance was five feet but there is no indication that the trial court (which did not cite this testimony but did cite the opposing evidence) credited the Gores' testimony.

<sup>2</sup> The factor of the rate of stretching was of direct interest to the examiner during the prosecution of the '566 patent. In response to the examiner's express request for a declaration that the Gore firm's production of stretched PTFE tape, prior to Robert Gore's invention asserted here, did not involve stretching of unsintered PTFE at a rate exceeding about 10% per second, Robert Gore filed an affidavit in the PTO specifically stating that "to my knowledge" (emphasis added) the 401 machine did not involve stretching at a rate exceeding about 10% per second.

<sup>3</sup> The 401 machine was used under the prior '915 patent (issued to Wilbert Gore) which contains no reference to the significance of the rate of stretch.

<sup>4</sup> Aside from the bases I discuss, I do not reach the other grounds asserted for invalidity of the '566 patent.

<sup>5</sup> Before the PTO Robert Gore concededly referred to this as "critical" to his invention or as his "invention."

<sup>6</sup> The District Court found that October 1969 was the earliest date Robert Gore asserts for his conception of the invention in the '566 patent.

cannot properly overturn that finding. But the absence of personal intent to defraud does not mean or say that, whether Robert Gore realized it or not, the 401 machine was not actually operating, well before October 1969, to stretch unsintered PTFE at a rate exceeding about 10% per second. Cf. *O'Brien v. Westinghouse Electric Corp.*, 293 F.2d 1, 10 (3rd Cir. 1961). It seems impossible to me to reconcile Robert Gore's insistence on two facts--that (i) he invented the process in October 1969 and (ii) he had no knowledge prior to October 1969 of stretching PTFE at the critical rate--with the solid facts in the record as to the prior operation of the 401 machine, except on the view that Robert Gore did not realize that he and others in the Gore shop had made his invention previously.

2. It follows that in October 1969 the invention of '566 would have been obvious under §103 to Robert Gore because the prior practice of the 401 machine constituted prior art. Even if this was not prior art technically within §102, that statutory provision "is not the only source of prior art." *In re Fout*, 675 F.2d 297, 300 (CCPA 1982, emphasis in original). The 401 machine was practiced under the '915 patent (issued to Wilbert Gore) and, whether or not Robert Gore subjectively realized what was happening, he and others in the Gore shop were practicing the invention later embodied in the '566 patent. That was prior art at least as to Robert Gore. *Id.* at 300-01.<sup>7</sup>

3. If it be thought necessary to invoke §102 directly, in order to show anticipation, the record contains proof that the 401 machine was designed, constructed and used (just as described supra) in November and December 1968 and the early months of 1969--more than one year prior to the '566 patent application of May 21, 1970. See *Jt. App. E 1199-E 1200*. Section 102(b) therefore applies. Although commercial production was apparently not actively sought until June 1969, the practicing of the 401 machine prior to May 21, 1969 was "a public use" because the Gore company made "use of the device \*\*\* in the factory in the regular course of business." *Connecticut Valley Enterprises, Inc. v. United States*, 348 F.2d 949, 952, 146 USPQ 404, 406 (Ct. Cl. 1965).

<sup>7</sup> The District Court has found that there are no differences between claim 1 of the '566 patent and the processes previously used by the Gore firm to produce paste-extruded unsintered PTFE.

4. Also, §102(a)<sup>8</sup> applies here because Robert Gore was the inventor in the '566 patent and Wilbert Gore and others in the Gore shop were using the 401 machine before October 1969. Wilbert Gore (the inventor in the '915 patent under which the 401 machine was made and used) and the other employees are "others" within §102(a)--they are not the same as Robert Gore who claimed to be inventor of the process that ripened into the '566 patent.<sup>9</sup> See also §102(f), which would bar Robert Gore if he did not himself invent the subject matter of the '566 patent.<sup>10</sup>

5. The majority sustains the validity of claims 3 and 19 of the '566 patent (the claims also involved in appellant's suit for infringement) which are dependent on invalid claim 1. Because of the invalidity of claim 1 the only possible novelty in claim 3 would be the requirement that the rate of stretch would be about 100% per second, and the possible novelty of claim 19 would be that the final length would be greater than about five times the original length. My position is that both of these added elements, if novel, would have been obvious to persons of ordinary skill in the art.

The defect in the majority's analysis is that it neglects the cardinal fact that the prior art included the 401 machine (discussed supra), not merely the earlier patents assessed in the majority opinion. The 401 machine directly involved PTFE itself, not conventional thermoplastic polymers. That machine also directly involved rapid stretching of PTFE at a rate markedly exceeding 10%. With this prior art of the 401 machine before him, an ordinary person skilled in the art would maximize stretch rate, if only to improve the machine's production rate. Cf. *In re Dwyer, Jewell, Johnson, McGrath, & Rubin*, 317 F.2d 203, 207, 137 USPQ 540 (CCPA 1963). Moreover, the very existence and operation of the 401 machine, which stretched PTFE rapidly without breaking, suggests to the skilled person the probability of stretching at even higher rates. Certainly, in the light of the 401 machine, skilled workers would see in at least

<sup>8</sup> An invention is anticipated if it "was known or used by others in this country \*\*\* before the invention thereof by the applicant for patent" (emphasis added).

<sup>9</sup> It is undisputed that it was Wilbert Gore who initiated the project for the 401 machine and watched over it.

<sup>10</sup> The majority's discussion of "secondary considerations," though it is relevant to other aspects of this case, is irrelevant to the issue of anticipation raised by the 401 machine, and hardly persuasive as to the issues of obviousness based on or with respect to the 401 machine.

the prior Markwood, Nash, and Scarlett patents (teaching extensive and rapid stretching of non-PTFE thermoplastics) the suggestion that the method of the 401 machine could also be used for comparable rapid and extensive stretching of PTFE.

6. In sum, I cannot escape the conclusion that—although there was no fraud proved—if the true facts as to the 401 machine had been made known to the PTO (as it requested), the involved claims of the '566 patent should (and probably would) not have been accepted.

### Court of Appeals, Second Circuit

Harper & Row, Publishers, Inc. et al.  
v. Nation Enterprises et al.

Nos. 83-7277 and 83-7327

Decided Nov. 17, 1983

## COPYRIGHTS

### 1. In general (§24.01)

Copyright Act sets out test for preemption of state statutory or common law that may conflict with federal policies embodied in Act.

### 2. Matter copyrightable — Classes in statute (§24.303)

Work of authorship in which rights are claimed must fall within "subject matter of copyright" as defined in Copyright Act Sections 102 and 103; Act embraces "works of authorship," including "literary works," as within its subject matter.

### 3. Matter copyrightable — In general (§24.301)

Fact that portions of memoirs may consist of uncopyrightable material does not take work as whole outside subject matter protected by Copyright Act; were this not so, states would be free to expand perimeters of copyright protection to their own liking, on theory that preemption would be no bar to state protection of material not meeting federal statutory standards; that interpretation would run directly afoul of one of Act's central purposes, to avoid development of any vague borderline areas between state and federal protection.

### 4. In general (§24.01)

Copyright Act requires that state law create legal or equitable rights that are equiv-

alent to any of exclusive rights within general scope of copyright as specified in Section 106 if it is to be preempted; these include rights to reproduce copyrighted work in copies, and to prepare derivative works based upon copyrighted work; when right defined by state law may be abridged by act that, in and of itself, would infringe one of exclusive rights, state law in question must be deemed preempted; conversely, when state law violation is predicated upon act incorporating elements beyond mere reproduction or the like, rights involved are not equivalent, and preemption will not occur.

### 5. Rights embraced in copyright (§24.50)

There is no qualitative difference between right of author and his licensed publishers to exercise and enjoy benefit of pre-book publication serialization rights, and exclusive right under Copyright Act of preparing derivative works based on copyrighted work; enjoyment of benefits from derivative use is so intimately bound up with right itself it could not possibly be deemed separate element.

### 6. In general (§24.01)

Fact that plaintiffs pleaded additional elements of awareness and intentional interference, not part of copyright infringement claim, in support of state law claim, goes merely to scope of right; it does not establish qualitatively different conduct on part of infringing party, nor fundamental non-equivalence between state and federal rights implicated.

### 7. Matter copyrightable — In general (§24.301)

Copyright Act protects only original works of authors; it grants rights not in ideas or facts, but in expression; one reasonable interpretation of word "discovery" in statute is "fact"; for example, historian who learns in his research that certain event has occurred has discovered fact; copyright does not preclude others from using ideas or information revealed by author's work; Act is thus able to protect authors without impeding public's access to information that gives meaning to our society's highly valued freedom of expression; neither news events, historical facts, nor facts of biographical nature are deserving of Act's protection; listing of names, nouns, or information is indisputably copyrightable as compilation, but preexisting facts contained in those lists are not protected.

### 8. Matter copyrightable — In general (§24.301)

Distinction between fact and expression is not always easy to draw; author's originality